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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,901	02/01/2005	Yoshinori Kuboki	AKY-0022	6659

23353 7590 04/09/2007  
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WASHINGTON, DC 20036

EXAMINER
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NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/522,901	KUBOKI, YOSHINORI	
	<b>Examiner</b>	<b>Art Unit</b>	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 01 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/1/05, 5/23/05</u> | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

A preliminary amendment of 2/1/05 amended claims 4 and 6-9.

Claims examined on the merits are 1-13, which are all claims in the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 1 of claim 1 and where recited in other claims "hard tissue" is uncertain as to meaning and scope. Being "hard" is relative and subjective.

In line 1 of claim 1 and where recited in other claims, "inductive scaffold" is uncertain as to meaning and scope. How does "inductive" define the scaffold, and how would one know when the scaffold is inductive and not inductive?

Bridging lines 1 and 2 of claim 1 and where recited in other claims "various implants" is unclear as to implants that are various implants. It is suggested "various" be canceled.

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In line 2 of claim 1 and where recited in other claims, "titanium group alloy fiber" is uncertain how "group" defines the alloy fiber. Materials that form the group are uncertain.

5 Bridging lines 3 and 4 of claim 1 and where recited in other claims, "materially designed to excel in biological hard tissue inductivity and fixing ability" is unclear as to meaning and scope, and it is uncertain how this limitation defines the scaffold. How one would know when a scaffold is materially designed as claimed is uncertain.

10 In line 4 of claim 1 and where recited in other claims, "fiber is selecting a fiber" is uncertain as to meaning.

In line 5 of claim 1 and where recited in other claims "short axis:long axis" is uncertain as to where the short and long axis are located.

15 In the last line of claim 1 and where recited in other claims "surface to inside" is unclear as to where the surface and inside are located.

Claim 2 is unclear how it further limits claim 1 since claim 2 is repeating structure that is already required in claim 1. A dependent  
20 claim should recite only how a preceding claim is further limited rather repeat what is already recited in the preceding claim.

In line 2 of claim 3 and where recited in other claims "apatite forming liquid" is uncertain as to meaning and scope. How does the liquid form the apatite?

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Dependent claims 6-8 are unclear as to whether the implant described is being required in combination with the scaffold of claim 1, or the claims are defining an implant that is capable of being used in combination with the scaffold.

5 Bridging lines 2 and 3 of claim 6, there is not clear antecedent basis for "the tooth".

In line 3 of claim 10, "winding up the layer to the artificial root" is unclear as to physical phenomena that constitutes "winding up".

10 Line 1 of claim 10 requires a method for proliferation of the scaffold. However, the claim does not require cells and proliferation of the cells. A scaffold cannot be proliferated.

In line 4 of claim 10, there is not antecedent basis for "the artificial root of the tooth". Additionally, does "winding up" also  
15 apply to the artificial joint?

In line 2 of claim 11, "using titanium fibers" is unclear since the claim is not directed to a method of use. In line 5, "providing cells of growing space" is unclear as to meaning.

***Claim Rejections - 35 USC § 102***

20 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

25 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vehof et al (document CB on 1449).

The claim is drawn to a scaffold for use with implants. The scaffold comprises layer composed of titanium fibers or titanium alloy fibers having a diameter smaller than 100  $\mu\text{m}$  and an aspect ratio of 20 or more.

Vehof et al discloses titanium fiber mesh loaded with bone morphogenetic protein and coated with calcium phosphate for use as a scaffold to form bone. The fibers have a diameter of 50  $\mu\text{m}$ , and the implant is in the shape of a disc having a diameter of 6 mm and a thickness of 0.8 mm. For example, see page 435 under "Materials and Methods".

The titanium fiber mesh in disc form of Vehof et al is a scaffold that is the same as presently claimed. It appears the fibers inherently have an aspect ratio as presently claimed. If not the same, it would have been obvious to vary the aspect ratio of the fibers of Vehof et al within limits that provide substantially the same results.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the  
10 invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner  
15 presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention  
20 was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vehof et al in view of Ducheyne (5,030,233) and  
25 White et al (3,890,107), and if necessary in further view of Okimatsu et al (EP 0 591 976 A1).

The claims require forming the scaffold by sintering the fibers under a vacuum. Claim 10 additionally requires winding the layer of fibers on the artificial root of a tooth or an artificial joint.

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Ducheyne discloses producing an implant by sintering metal fibers under a vacuum (col 8, lines 25-31).

White et al discloses sintered titanium fibers.

Okimatsu et al disclose sintering together metal fibers in a vacuum to produce an implant (paragraph bridging pages 2 and 3).

It would have been obvious to sinter fibers of the mesh of Vehof et al under a vacuum to fix the fibers together as suggested by Ducheyne sintering metals fibers under a vacuum to fix the fibers together and White et al disclosing sintered titanium fibers.

Combining the fibers with an artificial tooth root or an artificial joint as in claim 10 would have been obvious in view of prior art (Japanese Application Publication H8-140996 and H11-341) winding titanium fibers around an implant core to form a dentistry implant, and adhering a thin porous titanium metal to an implant, respectively, as described in the present specification (pages 2 and 3). If needed, Okimatsu et al would have further suggested sintering metal fibers in a vacuum to fix the fibers together to form an implant.

***Claim Rejections - 35 USC § 103***

Claims 3-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 2 and 10 above, and further in view of Kuboki et al (document CB on 1449 o9f 5/23/05) and Kuboki et al (4,812,404).

The claims require treating the fibers with an apatite forming liquid and coating with calcium phosphate containing hydroxyapatite or



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carbonateapatite. Claims 6-9 additionally define an implant used with the scaffold.

Kuboki et al (CB) discloses coating titanium dental implants with hydroxyapatite.

5 Kuboki et al ('404) disclose immobilizing glucanase on apatite for treating dental carries.

It would have been obvious to coat the fibers of Vehof et al with apatite as suggested by Kuboki et al ('404) using apatite in a composition for treating dental carries, and it would have been  
10 obvious to use hydroxyapatite to form the calcium phosphate coating on the fibers of Vehof et al as suggested by Kuboki et al (CB) coating titanium dental implants with hydroxyapatite. Using the scaffold with an implant as in claims 6-9 would have been obvious from prior art known as described in the present specification (pages 2 and 3) as set  
15 forth above in regard to claim 10.

***Claim Rejections - 35 USC § 103***

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vehof et al in view of Kuboki et al (CB) and Kuboki et al ('404).

20 The claims require a cell culture proliferation reactor containing the titanium fibers that have been treated with an apatite forming liquid and coating with calcium phosphate containing hydroxyapatite or carbonateapatite.

Vehof et al, Kuboki et al (CB) and Kuboki et al ('404) are  
25 described above.

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It would have been obvious to coat the fibers of Vehof et al with apatite suggested by Kuboki et al ('404) using apatite in a composition for treating dental carries, and it would have been obvious to use hydroxyapatite to form the calcium phosphate coating of Vehof et al on the fibers as suggested by Kuboki et al (CB) coating titanium dental implants with hydroxyapatite. The titanium mesh of Vehof et al is inherently a cell culture proliferation reactor.

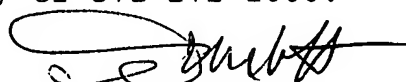
### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff  
Primary Examiner  
Art Unit 1657

DMN

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